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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/677,718	10/02/2003	Dean McCormack Peterson	929.001US2	9187

7590 09/14/2006

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EXAMINER

MEHTA, BHISMA

ART UNIT PAPER NUMBER

3767

DATE MAILED: 09/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/677,718	Applicant(s) PETERSON, DEAN MCCORMACK	
	Examiner Bhisma Mehta	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 30-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 30-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>2/23/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the access ports for accessing information from a memory unit and an electrical pump attached to the therapy bag must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 39, 33, 31, 27, 29, 35', 37, 35, 30, 220, 340, 400, 408, 500, 516, and 518. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 30' and 26'. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

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the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose a memory storage element.

5. The disclosure is objected to because of the following informalities:

The amendments to pages 12 and 14-15 in the specification, received October 2 2003, are unclear because it appears that these amendments are in reference to pages 15 and 20-21 of the specification.

In line 22 of page 6, the word "tome" is misspelled and there appears to be a spelling mistake in line 29 of page 7 with the phrase "paint control". Also, there are multiple grammatical errors in lines 6-9 of page 18. In line 18 of page 22, the word "servoing" is misspelled. In line 3 of page 23, "141" should be "14".

There are numerous instances where a reference character has been used to designate two separate things. For example, in lines 4-6 of page 15, reference character 35 has been used for flush receiving grooves and for a central segment. Similarly, reference character 24' has been used for a therapy bag in line 23 of page 14 and for an access port in line 18 of page 15. These errors also occur with the following reference characters: 43' (an area adjacent to the flush receiving grooves and an

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access port), 32 (a fill port and an input connector), 34 (an access port and an output connector), 16 (a set and a set tubing), 44 (a chip and an electrical connector), 94 (a spur gear and an intentional gap), 34' (an access port and an output connector), 32' (a fill port and an input connector), 37' (a rear portion and a mating recess), 322 and 324 (stub tubes and ports), 366 (a memory/read system and a dock), and 12 (a pump unit and a pump).

Appropriate correction is required.

6. The abstract of the disclosure is objected to because it is too long. Correction is required. See MPEP § 608.01(b).

Claim Objections

7. Claims 30-34, and 38-40 are objected to because of the following informalities: Claim 30 recites the limitation "said flexible therapy bag" in lines 7-8. Claims 31 and 32 recite the limitation "said memory unit" in lines 4 and 1, respectively; however, the memory unit is not positively recited in line 4 of claim 31. Claim 40 recites the limitations "said memory chip", "said infusion therapy apparatus", "said infusion apparatus" and "said therapeutic fluid" in lines 1-4. There is insufficient antecedent basis for these limitations in these claims. Also, there are two claims numbered "38". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 31-34, 38, and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 31, it is unclear if the fluid control element in line 2 refers to the fluid control element recited in line 9 of claim 30 or an additional fluid control element is being established. Also, in claim 31, it is unclear if a storage area for a memory unit and access ports is being claimed or if the access ports themselves are being claimed. The dependency of claim 38 is unclear because both of the claims numbered 38 recite "the therapy infusion apparatus" and depend from claims 35 and 36. However, claims 35 and 36 are for a therapy bag. Also, the dependency of claim 39 is unclear as claim 39 recites "the therapy bag" but refers back to claim 30.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 30-33 and 35-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Stoker et al (U.S. Patent No. 5,807,321). Stoker et al disclose a therapy infusion apparatus having a therapy bag (14'), an exit port (20') which is in communication with a memory storage element (106), and an adjustable fluid control

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element (100). The memory storage element (106) is capable of storing information relating to at least one of identification of a patient and name of a medication (see lines see lines 1-16 of column 14 and lines 44-67 of column 24). In Figure 3, two flow ports (22') within the fluid control element (100) are shown. One of the ports is the exit port (20') and adjacent to at least one of the ports is a storage area (108) for a memory unit and access ports (274) for accessing information from the memory unit. The memory unit (220) comprises a chip or microprocessor and the access ports enable electronic connection from an outside memory reading or memory writing apparatus to the chip (see lines 17-41 of column 14). The chip which is present in the storage area contains readable information relating to at least the volume of a prescription (lines 6-11 of column 14), a patient name or patient I.D. (lines 54-57 of column 24), instructions for a flow control module with respect to desired flow rates (lines 26-29 of column 14), rate and volume of delivery (lines 10-21 of column 8), and drip rate (lines 10-21 of column 8). As to claim 35, Stoker et al disclose a therapy bag having a flexible bag (14') with a fluid storage area, a memory element storage area (106) and a delivery end (20') with two fluid ports (22'). At least one of the ports is capable of allowing fluid flow from within the fluid storage area. the delivery end has the memory element storage area (108) with a memory element or chip (220) which has access ports (274) for electronically accessing the memory element (220). The memory element is writeable (see lines 17-41 of column 14). As to claim 37, the memory storage element is asymmetrically located along the delivery end as seen in Figure 2. As to claim 39, in lines 54-62 of column 17, Stoker et disclose a battery which provides power to the various electrical

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components of the device which include a display panel, a chip, a light emitting diode display, and a fluid control element. As to claim 40, Stoker et al teach that the memory element or chip (22) is capable of being programmed wherein information can be entered for storage in the memory chip relating to the fluid which is being delivered to a patient (lines 6-24 of column 8).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stoker et al in view of Gray (U.S. Patent No. 5,980,501). Stoker et al disclose the infusion apparatus substantially as claimed. However, Stoker et al are silent on an electrical pump attached to the therapy bag to move liquid from the therapy bag. Gray discloses an infusion apparatus having an electrical pump in the form of a peristaltic pump coupled to a microprocessor which is used to deliver liquid to a patient. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the infusion apparatus of Stoker et al with the electrical pump as taught by Gray as the electrical pump of Gray coupled to the memory element or chip of Stoker et al would aid in the electronic monitoring of the fluid to the patient.

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 30-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 6,641,562. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are drawn to infusion apparatus having a therapy bag, exit port, and an adjustable fluid control element.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Frank et al (U.S. Patent No. 5,211,626), Ross et al (U.S. Patent No. 5,308,335), and Campbell et al (U.S. Patent No. 5,342,313) disclose infusion apparatus having a therapy bag.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bhisma Mehta whose telephone number is 571-272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



BM

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

